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OFFICE OF INTERNATIONAL CORPORATE <u>FINANCE</u>

10 December 2004



Ventracor Limited

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Securities and Exchange Commission Division of Corporate Finance Office of International Corporation Finance 450 Fifth Street, NW WASHINGTON DC 20549 USA



Dear Ladies and Gentleman

Re:

Ventracor Limited

File # 82-4630

Ventracor Limited (the "Company") is furnishing herewith information pursuant to Rule 12g3-2(b)(1)(i) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The attached documents are being furnished with the understanding that they will not be deemed "filed" with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, and that neither this letter nor the furnishing of such documents shall constitute an admission for any purpose that the Company is subject to the Exchange Act.

If you have any questions or comments please call the undersigned at (61) 02 9406 3100.

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Very truly yours

per K. Callafon

Andrew Geddes
Corporate Communications

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Ventracor CE Mark Trial Disclosure Protocol

<u>Sydney 10 December 2004:</u> Ventracor Limited (ASX:VCR) today provided guidance on market announcements for the CE Mark Trial currently underway.

Ventracor Chief Executive Officer, Colin Sutton PhD, said: "In compliance with Australian Stock Exchange requirements for full and fair disclosure, Ventracor advises the market of our policies and principles." Dr Sutton said all stakeholders should note:

- The company's goal is to ensure the market is kept progressively informed on a timely and accurate basis of material developments.
- The company is aware of its obligations under ASX Listing Rule 3.1 and, in the absence of material developments relevant to the progress of the trial, reports to the market will be on an ongoing periodic basis.
- Ventracor is working closely with the Australian Stock Exchange to ensure clarity, consistency and timeliness of all public information.
- Ventracor is committed to the privacy, dignity and wellbeing of individual patients and their families.
- The CE Mark Trial is the last step in product validation to statistically demonstrate the VentrAssist™ is safe and efficacious for its first intended market – Europe.
- Clinical trials involve a trade off of risk and benefit. Adverse events are to be expected, particularly
 in destination therapy where all patients will eventually pass away with the device implanted
 irrespective of the good functioning of the VentrAssist™.
- Only the final statistical analysis of the completed trial will demonstrate the safety and efficacy of the VentrAssist. Interim analyses are always non-representative.

CE Mark Trial centers

The trial is being conducted at leading transplant hospitals in Europe, New Zealand, and Australia.

The CE marking approval process is well defined by European Union legislation and there are clear and achievable steps involving validation of design process, bench testing and clinical performance.

The trial will be run according to clearly defined international Good Clinical Practice (GCP) guidelines and the highest safety, medical and scientific guidelines set out by standards defined by the Declaration of Helsinki and European Commission.

Ventracor is the trial sponsor and responsible for supplying the technology and ultimately accumulating trial data to support regulatory approval.

Medical investigators at participating hospitals are responsible for recruitment, surgical procedures and medical care.

Gaining approval to apply the CE mark to the VentrAssist will allow Ventracor to sell the device for use in Europe, and with further regulatory submissions in Australia and New Zealand. The start of the company's planned US clinical trials program will begin before the end of the CE Mark Trial.

Disclosure of individual patient details and specific outcomes contravenes *The Privacy Act (1988)*. Individual patient outcomes are very important but will not necessarily reflect on the outcome of the entire trial. Accordingly, Ventracor will report at various points during the trial and not on a case by case basis.

Guiding principles

As a world leading company in artificial heart technology, integrity and excellence are fundamental to Ventracor Limited. We are mindful of the great benefit our technology brings to patients enrolled in the clinical trials and its potential to benefit many more people who suffer end stage heart failure.

The dignity, safety, wellbeing and privacy of all patients are of primary concern to the Company. In line with this concern the Company has adopted the following principles for the benefit of all stakeholders.

- 1. We will pursue medical technology in line with the highest medical, ethical and safety standards, protocols and guidelines and our company values, as well as our legal and ASX obligations.
- We recognise the unique scientific, philosophical and ethical implications of medical technology must be considered at all times.
- 3. We respect the privacy, dignity and wellbeing of our patients and their families at all times.
- 4. We will do our utmost to ensure patients and their families are fully informed about the relevant benefits, risks and potential implications of the VentrAssist™ system.
- 5. We will ensure the scientific integrity of the clinical trials.
- 6. We will support and work closely and effectively with our partner medical teams in conducting the clinical trials in the best possible environment.
- 7. We will actively listen to and treat with the utmost respect all stakeholders in an effort to understand their concerns and to help us progress in a responsible and timely way

For more information please contact

Ventracor Limited 02 9406 3100



asx announcement

Ventracor Market Disclosure - CE Mark Trial

<u>Sydney 10 December 2004:</u> Ventracor Limited (ASX:VCR) today announced its policy on announcements during product registration trials including the current CE Mark Trial.

Ventracor Limited Chief Executive Officer Colin Sutton PhD said, "The Pilot Trial has demonstrated the VentrAssist™ system can be safely used in an international patient population for our CE product registration trial.

"In making the transition from a pilot trial to a product registration trial, our method of reporting progress in these trials will necessarily change.

"Ventracor's primary goal is to rapidly commercialise the VentrAssist system and thus to realise revenues from sales of the system in the shortest period possible.

"The company's record in taking an entirely new (third) generation system from concept to clinical trials in five years is unparalleled.

"Our CE registration trial will also be one of the most efficient trials conducted in the industry", said Dr Sutton.

The independent statistician for the CE Mark Trial, Professor Val Gebski of the Sydney-based National Health and Medical Research Council (NH&MRC) Clinical Trials Centre said: "The design of the CE Mark Trial and the science underpinning the results requires consideration of outcomes after a certain number of patients have been entered, assessed and followed.

"By avoiding commenting on individual outcomes and with a single final report at completion, the clinical trial can be kept small and finish in the minimum time.

"It is inappropriate to release interim reports of the outcome of individual cases as this can potentially compromise the science of the study and affect patient recruitment as interim information is subject to change resulting in incorrect inferences being drawn," Professor Gebski said.

Dr Sutton emphasized the company was aware of its obligations under ASX Listing Rule 3.1 and, in the absence of material developments relevant to the progress of the trial, clinical reports released to the market will be on an ongoing periodic basis.

"Ventracor anticipates keeping the market apprised of progress in the commercialisation of the VentrAssist in the near future.

"This will include progress toward commencement of trials in the United States, a new series of patents for product enhancements, completion of in-house manufacturing and distribution agreements currently under negotiation," Dr Sutton said.